Vaccine Development - From Bench to Mass Production (Epidemic Focus) Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

This intensive two-paragraph introduction targets professionals seeking to master the accelerated vaccinology roadmap in the face of global health threats. The recent surge in emerging infectious diseases necessitates a paradigm shift toward rapid response platforms and biomanufacturing scalability. Vaccine Development - From Bench to Mass Production (Epidemic Focus) Training Course is engineered to bridge the knowledge gap between immunology discovery and global distribution logistics, focusing heavily on pandemic preparedness. Participants will gain expertise in cutting-edge technologies like mRNA and viral vector vaccines, understanding the critical regulatory pathways, including Emergency Use Authorization (EUA), that compress conventional 10-year timelines into months.

The curriculum places a unique emphasis on the entire end-to-end value chain, starting from antigen selection and pre-clinical development, through adaptive clinical trial design, and culminating in current Good Manufacturing Practices (cGMP) and cold chain integrity. By integrating pharmacovigilance and public health policy, we equip leaders to navigate complex geopolitical and ethical considerations, ensuring immunization equity and addressing vaccine hesitancy. This training is essential for professionals dedicated to strengthening health system resilience and leading the next generation of global health security initiatives.

Programme Curriculum

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Course Objectives

1. Master the principles of mRNA and Adenoviral Vector platform technologies for rapid deployment.
2. Design accelerated clinical trial protocols specific to epidemic scenarios.
3. Analyze antigen selection and optimization strategies based on immune response modeling.
4. Implement cGMP compliant scale-up procedures for high-volume biomanufacturing.
5. Evaluate fill-finish and sterility assurance protocols in high-speed production environments.
6. Navigate global regulatory pathways, including FDA Biologics License Application (BLA) and WHO prequalification.
7. Develop robust cold chain and ultra-low temperature distribution strategies for sensitive biologics.
8. Apply risk management frameworks across the vaccine lifecycle, from lab safety to community deployment.
9. Integrate digital tracking and pharmacovigilance systems for real-time post-market surveillance.
10. Formulate strategies to overcome supply chain vulnerabilities and enhance regional manufacturing capacity.
11. Address ethical considerations, focusing on health equity and equitable access in low-resource settings.
12. Communicate vaccine safety and efficacy data effectively to counter vaccine misinformation.
13. Leverage artificial intelligence (AI) in predicting outbreak trajectories and accelerating target identification.

Target Audience

1. Biopharma Scientists (R&D, Process Development).
2. Clinical Research Associates (CRAs) and Trial Managers.
3. Quality Assurance/Control (QA/QC) Professionals.
4. Supply Chain and Logistics Directors.
5. Public Health Officials and Epidemiologists.
6. Bioprocess Engineers and Manufacturing Technicians.
7. Regulatory Affairs Specialists.
8. Government and NGO Policy Makers focused on Global Health.

Course Modules

Module 1: Foundational Vaccinology & Pathogen Identification

- Immunological basics.
- Understanding the R-nought (R0?Çï) and disease transmission modeling.
- Antigen selection criteria for emerging viral threats.
- Introduction to bioinformatics and genomic surveillance tools.
- Case Study: The rapid identification of the SARS-CoV-2 Spike protein as the primary target antigen.

Module 2: Emerging Vaccine Platform Technologies

- Mechanism of action and stability of mRNA vaccines.
- Design and production of viral vector vaccines
- Principles of protein subunit and virus-like particle (VLP) platforms.
- Comparative analysis of platform advantages for speed and cost.
- Case Study: Comparing the development timelines and efficacy of the Pfizer-BioNTech (mRNA) vs. AstraZeneca (Viral Vector) COVID-19 platforms.

Module 3: Pre-Clinical Development & IND Preparation

- In vitro and in vivo testing for immunogenicity and efficacy.
- Toxicology and GLP (Good Laboratory Practice) requirements for animal models.
- Developing the Investigational New Drug (IND) application dossier.
- Establishing pre-clinical safety thresholds and dosage ranges.
- Case Study: Analyzing the pre-clinical data package that led to the FDA's acceptance of the first MERS-CoV vaccine candidate IND.

Module 4: Adaptive Clinical Trial Design for Pandemics

- Safety and dose-finding in a small cohort.
- Seamless and adaptive trial design protocols
- Statistical considerations for calculating vaccine efficacy (VE) rapidly.
- Designing placebo-controlled versus head-to-head trials in crisis.
- Case Study: The COVAX platform and the challenge of running placebo-controlled trials once an effective vaccine is available.

Module 5: Regulatory Affairs & Emergency Use Authorization (EUA)

- Global regulatory frameworks.
- The criteria and process for securing Emergency Use Authorization (EUA).
- Transitioning from EUA to full Biologics License Application (BLA).
- Data requirements for chemistry, manufacturing, and controls (CMC).
- Case Study: Reviewing the regulatory pathway for the J&J single-dose viral vector vaccine EUA submission.

Module 6: cGMP Manufacturing and Quality Systems

- Fundamentals of Current Good Manufacturing Practices (cGMP) compliance.
- Establishing a robust Quality Management System (QMS) in a high-speed environment.
- Facility design: Cleanroom classifications and cross-contamination prevention.
- Validation protocols for equipment, processes, and cleaning.

- Case Study: Identifying non-compliance risks during rapid expansion of a legacy manufacturing site for pandemic response.

Module 7: Upstream Bioprocess Scale-Up

- Cell line selection and optimization for high-yield expression (CHO cells, yeast).
- Process intensification strategies: high-density cell culture and perfusion systems.
- Viral seed stock preparation and master/working cell bank protocols.
- Bioreactor scale-up calculation and geometric similitude.
- Case Study: Overcoming bioreactor contamination issues during the 2009 H1N1 influenza vaccine scale-up.

Module 8: Downstream Purification and Bulk Drug Substance

- Chromatography techniques for high purity.
- Virus inactivation and removal strategies for product safety.
- Tangential Flow Filtration and ultrafiltration for concentration and buffer exchange.
- Formulation development
- Case Study: Analyzing the impact of Lipid Nanoparticle (LNP) formulation stability on mRNA vaccine storage requirements.

Module 9: Aseptic Fill-Finish and Device Assembly

- Aseptic processing principles and cleanroom gowning requirements.
- High-speed vial and syringe filling line operations.
- Lyophilization cycles for vaccine stability.
- Inspection, labeling, and secondary packaging automation.
- Case Study: Managing glass delamination and particle contamination issues during high-throughput fill-finish operations.

Module 10: Supply Chain & Cold Chain Management

- Designing ultra-cold chain logistics (UCC) for mRNA products (-70?êÿC).
- Modeling and mitigating risks associated with "the last mile" delivery in low-resource settings.
- Monitoring and real-time temperature tracking technologies (IoT sensors).
- Strategic stockpiling and inventory management for surge capacity.
- Case Study: The successful deployment of the COVID-19 vaccine to remote locations in Africa despite temperature constraints.

Module 11: Global Deployment and Public Health Policy

- WHO's Immunization Agenda 2030 (IA2030) and Universal Health Coverage targets.
- Mechanism of COVAX and Gavi for equitable vaccine distribution.
- Country-level planning.
- Addressing access barriers and overcoming geographical disparities.
- Case Study: The challenges faced by the COVAX facility in balancing donor country priority and global equity targets.

Module 12: Pharmacovigilance and Safety Monitoring

- Setting up active and passive post-marketing surveillance systems
- Identifying and investigating Adverse Events of Special Interest (AESI).

- Risk-Benefit analysis and signal detection methodology.
- Regulatory actions: label changes, recalls, and continuous monitoring.
- Case Study: The swift investigation and public communication following reports of thrombosis associated with a specific viral vector vaccine.

Module 13: Ethical, Social, and Communication Challenges

- Ethical frameworks for clinical trials during a public health emergency.
- Strategies for combating vaccine hesitancy and building public trust.
- Effective risk communication models for media and public dissemination.
- Intellectual property (IP) waivers and technology transfer debates.
- Case Study: Analyzing the public communication failures and successes of major health organizations during a simulated outbreak.

Module 14: Biosecurity and Next-Generation Tools

- Pandemic Treaty initiatives and international legal frameworks.
- The role of AI/Machine Learning in predictive epidemiology and drug discovery.
- Development of Universal Vaccines against pan-coronavirus or pan-influenza threats.
- Emerging delivery systems.
- Case Study: Evaluating a country's readiness score based on its Biosecurity Act and laboratory audit results.

Module 15: Financial Modeling and Project Leadership

- Cost-of-Goods-Sold analysis and pricing strategies for public health.
- Securing public-private partnership funding and grant mechanisms.
- Project management methodologies for accelerated timelines
- Developing a sustainable business model for regional vaccine hubs.
- Case Study: Creating a budget and timeline for establishing a novel mRNA production facility in a developing country.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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